

**DEPARTMENT OF HEALTH SERVICES**

GENETIC DISEASE BRANCH  
2151 BERKELEY WAY, ANNEX 4  
BERKELEY, CA 94704



**Newborn Screening Program**  
**Tandem Mass Spectrometry (MS/MS) Research Project**  
*Informed Consent Protocol*

**Roles & Responsibilities:**

***Prenatal Care Providers and Birth Attendants*** are required by law to distribute a copy of the informational material, *Important Information for Parents About the Newborn Screening Test*. The revised booklet, which describes both the current mandatory Newborn Screening Program and the supplemental voluntary screening through the research study, should be distributed to mothers who are due to deliver on or after January 7, 2002. Providers should be available to reinforce the information about the voluntary supplemental screening and encourage participation in the project.

***Pediatric Care Providers*** should be available to reinforce the information about the voluntary supplemental screening and encourage participation in the project.

***Hospital Staff*** will distribute the revised booklet about Newborn Screening to all mothers who present for delivery on or after January 7, 2002 and verify consent by having mothers indicate whether they wish to participate in the voluntary screening.

**Suggested Protocol:**

<b><i>Responsible Person</i></b>	<b><i>Action</i></b>
Prenatal Care Provider	<ul style="list-style-type: none"> <li>• Displays MS/MS Program Poster provided by DHS in patient waiting areas.</li> <li>• Early in the third trimester of prenatal care distributes a copy of the informational Newborn Screening program booklet entitled <i>Important Information for Parents about the Newborn Screening Test</i>, containing information on mandatory and voluntary supplemental program, to woman/parents. (See attached "Script" for discussion).</li> <li>• Discusses voluntary supplemental program and answers questions as needed.</li> </ul>
Hospital/Birthing Center, Labor and Delivery, Antepartum and/or Postpartum, Nursery Staff	<ul style="list-style-type: none"> <li>• Displays MS/MS Program Poster provided by DHS in a public area</li> <li>• Provides families during their hospital stay with informational Newborn Screening program booklet entitled <i>Important Information for Parents about the Newborn Screening Test</i>, containing information on mandatory and voluntary supplemental program, to woman/parents.</li> </ul>

<p>Hospital/Birthing Center, Labor and Delivery, Antepartum and/or Postpartum, Nursery Staff (Continued)</p>	<ul style="list-style-type: none"> <li>• Verifies informed consent and asks woman/parents to sign Informed Consent document contained in informational booklet. Assures that either the “Yes” or “No” statement on Consent Form is marked for participation or refusal to participate. If additional information is needed or if woman/parents have questions, answers questions or refers questions to attending physicians in accordance with hospital policy (<b>NOTE:</b> Hospital may choose to have a physician available on site or by phone to assist in answering questions). <b><i>If woman/parents have unanswered questions or unresolved issues regarding the supplemental research project at the time of specimen collection, marks box indicating refusal to participate and obtains signature, and puts a “no” sticker on the form.</i></b></li> <li>• Completes Newborn Screening Test Request Form (TRF) with all demographic information.</li> <li>• Indicates whether parents want their newborn to have supplemental testing by affixing each half of the color-coded sticker (indicating “<b>YES</b>” or “<b>NO</b>”) first to the <b><i>demographic portion</i></b> and then the <b><i>filter paper portion</i></b> at least one inch from the blood collection circles of the Newborn Screening Collection Form.</li> <li>• Collects heelstick blood specimen onto the five circles on the filter paper for Newborn Screening on babies between 12 hours and the 6<sup>th</sup> day of age.</li> <li>• Allows filter paper to dry per protocols and sends to NAPS Lab for processing.</li> <li>• Files original of Informed Consent form for supplemental testing in newborn’s medical record along with goldenrod color copy of TRF.</li> <li>• Gives copy of Informed Consent form to woman/parents.</li> </ul>
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